APR 2 9 2004

K040008

XI. SUMMARY OF SAFETY AND EFFECTIVENESS

Product:
QuickVue® Advance pH and Amines gII test

Manufacturer:
QUIDEL Corporation
10165 McKellar Court
San Diego, California 92121
U.S.A.

Device Classification:
Urinary pH (nonquantitative) test system
21 CFR 862.1550
Class I

Intended Use:
The QuickVue Advance pH and Amines gII test contains two qualitative, colorimetric tests for use in the characterization of a vaginal fluid sample: (1) a pH test that differentiates vaginal fluid pH < 4.7 from vaginal fluid pH $\geq$ 4.7; and (2) a test that detects alkali volatilizable amines in vaginal fluid. The test is intended for use by health care professionals as an aid in the diagnosis of bacterial vaginosis.

Principles of the Test:
pH Test: The pH test contains a colorimetric pH indicator, which produces a visual color change within one minute of sample application. When contacted with a vaginal fluid sample at or above pH 4.7, the pH test area produces a distinct greenish-blue plus sign against a yellow background and a greenish-blue procedural control dot in the test area. When contacted with a vaginal fluid sample lower than pH 4.7, the pH test produces only a greenish-blue procedural control dot, within one minute, against a yellow background in the test area. Any test that does not develop a procedural control dot is considered an invalid result.

Amines Test: The QuickVue Advance Amines gII test contains a colorimetric pH indicator, which produces a visual color change within one minute of sample application. The test employs a film of BCG in the yellow test area that is surrounded by a thick black ring covered with a dried alkali analogous to the potassium hydroxide (KOH) used to perform the whiff test. The amines test area produces a distinct greenish-blue plus sign against a yellow background within one minute and a greenish-blue procedural control dot in the test area when contacted with a vaginal fluid specimen containing volatile amines at concentrations above 0.5 mM. When contacted with a vaginal fluid specimen that does not contain alkali volatilizable amines, the amines test produces a greenish-blue procedural control dot against a yellow background in the test area (within one minute). Any test that does not develop a procedural control dot is considered an invalid result.

Safety and Effectiveness:
Numerous studies were undertaken to validate the performance characteristics and the substantial equivalence of the QuickVue Advance pH and Amines gII test. These studies included the following:

1. The test was shown to have excellent intra- and inter-assay precision.
2. Lot-to-lot consistency analyses showed the test to be reproducibly manufacturable.
3. Potentially interfering substances were shown not to interfere.
4. A multi-center field clinical study was conducted. Sensitivity, specificity and overall accuracy relative to the Amsel criteria with resolution by Gram stain were calculated.
5. Physicians' Office Laboratory studies were conducted to show that physician office personnel could perform the test accurately and reproducibly. Testing was performed at three geographically distinct sites in the United States.

Conclusion:
These studies demonstrated the substantial equivalence of the QuickVue Advance pH and Amines gII test to existing products already marketed, including the FemExam TestCard test [510(k) K962718], also sold under the brand name QuickVue Advance pH and Amines test. They further demonstrated the suitability of the product for laboratory and professional use. Such studies are a critical element in establishing the fundamental safety and effectiveness of the product and its appropriateness for commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 2 9 2004

Ms. Jennifer S. Hankard
Regulatory Affairs Manager
Quidel Corp.
10165 McKellar Ct.
San Diego, CA 92121

Re: k040008
Trade/Device Name: QuickVue® Advanced pH and Amines gII test
Regulation Number: 21 CFR 862.1550
Regulation Name: Urinary pH (nonquantitative) test system
Regulatory Class: Class I
Product Code: CEN
Dated: March 24, 2004
Received: March 30, 2004

Dear Ms. Hankard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040008

Device Name: QuickVue® Advance pH and Amines gII test

Indications For Use:

The QuickVue Advance pH and Amines gII test contains two colorimetric tests intended for the qualitative detection of elevated vaginal fluid pH (pH $\geq$ 4.7) and the presence of volatile vaginal fluid amines. The test is intended for use by health care professionals as an aid in the diagnosis of bacterial vaginosis.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) 040008